Ortho-Clinical Diagnostics
a Johnson-Johnson company

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NOV 2 2 2006

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5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K062637

1. Submitter name, address, contact	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (585) 453-4253 Contact Person: Darlene Phillips
2. Preparation Date	September 1, 2006
3. Device name	**Trade or Proprietary Names:** VITROS Chemistry Products METD Reagent VITROS Chemistry Products Calibrator Kit 26 VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV & V **Common Names**: Methadone (METD) assay and controls **Classification Names:** Methadone test system (862.3620) Class II Clinical toxicology calibrators (862.3200) Class II Clinical toxicology control material (862.3280) Class I, VITROS DAT Performance Verifiers are assayed controls, so they meet the reserved criteria under Section 510(l) of the Food, Drug and Cosmetic Act.
4. Predicate Devices	The VITROS Chemistry Products METD assay is substantially equivalent to the EMIT® II Plus Methadone Assay. The VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the BIO-RAD Liquichek™ Urine Toxicology Controls.

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510(k) Summary (continued)

5. Device description

The VITROS METD assay is a homogeneous enzyme immunoassay that is performed using the VITROS Chemistry Products METD Reagent in conjunction with the VITROS Chemistry Products Calibrator Kit 26 and VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent/DAT Diluent 2) on VITROS 5,1 FS Chemistry Systems.

The VITROS METD Reagent is a dual chambered package containing ready-to-use liquid reagents that are used to detect methadone in urine. Sample, calibrators, and controls are automatically treated with surfactant (DAT Diluent 2) prior to addition of reagents. Treated sample is added to Reagent 1 containing antibodies reactive to methadone, glucose-6-phosphate and nicotinamide adenine dinucleotide (NAD^+), followed by Reagent 2 containing methadone labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH). The assay is based on competition between methadone in the treated urine sample and the methadone labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, therefore the concentration of methadone in the urine sample is directly proportional to measured enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD^+) to NADH, resulting in an absorbance change that is measured spectrophotometrically at 340 nm.

VITROS Chemistry Products Calibrator Kit 26 is prepared from human urine to which drugs of abuse, metabolites of drugs of abuse, organic salt, surfactants, and preservative have been added. VITROS Calibrator Kit 26 is a single fluid and from it six dilutions are performed by the VITROS 5,1 FS Chemistry System to create a total of six calibrators. These standards are used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of methadone (METD).

VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV and V are prepared from a human urine pool to which analytes, surfactant, and preservative have been added. These are assayed controls used to monitor performance of the VITROS METD assay on VITROS 5,1 FS Chemistry Systems.

The VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent/ DAT Diluent 2) is a common reagent that is used with several drugs of abuse assays to dilute calibrators and samples on the VITROS 5,1 FS System. This is a dual chambered package containing two ready-to-use liquid diluents. DAT Diluent is prepared from human urine to which organic salt, surfactants, and preservative have been added. DAT Diluent 2 is prepared from processed water to which surfactant and preservative have been added.

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5. Device description *(continued)*

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) premarket notification (K031924).

6. Device intended uses

VITROS Chemistry Products METD Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products METD Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of methadone (METD) in human urine using a cutoff of either 150 ng/mL or 300 ng/mL. Measurements obtained with the VITROS METD method are used in the diagnosis and treatment of methadone use or overdose.

The VITROS Chemistry Products METD assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

VITROS Chemistry Products Calibrator Kit 26: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV and V: For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

7. Comparison to predicate devices

The VITROS Chemistry Products METD assay and VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the EMIT® II Plus Methadone Assay (K010962) and BIO-RAD Liquichek™ Urine Toxicology Controls (K022707) (predicate devices) which were cleared by the FDA for in vitro diagnostic use.

The performance of the VITROS METD assay on the VITROS 5,1 FS Chemistry System was compared to the EMIT® II Plus Methadone assay on the OLYMPUS® AU400 System. The results demonstrated good agreement between the two immunoassay methods.

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510(k) Summary (continued)

The VITROS METD assay and the VITROS DAT Performance Verifiers have the following similarities to the predicate devices: the same intended use, the same cutoff values of 150 and 300 ng/mL, consist of liquid, ready to use reagents, have similar performance characteristics, are used on an automated clinical chemistry analyzer and calibrated against the same drug, methadone.

Table 1 Similarities and differences of the assays performed using the new and predicate devices..

Device Similarities	
Device Characteristic	**Description**
Indications for Use	The assays are intended for use in the qualitative and semi-quantitative analysis of methadone in human urine.
Test Principle	Homogeneous enzyme immunoassay
Cut-Off values	150 and 300 ng/mL
Sample Type	Human Urine
Reagent Format	Liquid ready to use
Antibody source	Sheep polyclonal antibodies reactive to methadone
Calibration traceability	Methadone
Calibrator matrix	Human urine
Control matrix	Human urine

Differences		
Device Characteristic	**VITROS METD assay (New device)**	**EMIT® Methadone assay and Liquichek™ Controls (Predicate devices)**
Number of Calibrator levels	Six	Four
Calibrator format	Frozen Liquid ready to use	Refrigerated liquid ready to use
Instrumentation	VITROS 5,1 FS Chemistry Systems	Multiple OLYMPUS analyzers
Control claimed analytes	Cocaine metabolites (benzoylecgonine), benzodiazepines (lormetazepam), methadone, amphetamines (d-methamphetamine), opiates (morphine), cannabinoids (11-nor-delta-THC-9-COOH), phencyclidine and barbiturates (secobarbital).	Methamphetamine, secobarbital, lormetazepam, tetrahydrocannabinol (THC), benzoylecgonine, ethanol, lysergic acid diethylamide (LSD), methadone, methaqualone, morphine, (Free), phencyclidine, propoxyphene, nortriptyline and addition of creatinine, pH, specific gravity.
Control: Number of levels	Five	Two

510(k) Summary (continued)

8. Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products METD Reagent, VITROS Chemistry Products Calibrator Kit 26 and VITROS Chemistry Products DAT Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Darlene J. Phillips
Regulatory Associate
100 Indigo Creek Drive
Rochester, New York 14626-5101

NOV 2 2 2006

Re: k062637
Trade/Device Name: VITROS Chemistry Products METD Reagent
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR, DKB, DIF
Dated: September 1, 2006
Received: September 5, 2006

Dear Ms. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062637

Device Name: VITROS Chemistry Products METD Reagent

Indications for Use:

VITROS Chemistry Products METD Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of methadone (METD) in human urine using a cutoff of either 150 ng/mL or 300 ng/mL. Measurements obtained with the VITROS METD method are used in the diagnosis and treatment of methadone use or overdose.

The VITROS Chemistry Products METD assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional) K062637

Indications for Use

510(k) Number (if known): K062637

Device Name: VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV and V

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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